K011529

Special 510(k) Summary of Safety and Effectiveness: Device Modifications to the Osteo IC Humeral Nail System Nail

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	May 15, 2001

Device Identification

Proprietary Name:	T2 Humeral Nail System (formerly the Osteo IC Humeral Nail System)
Common Name:	Intramedullary Nail, Humeral Nail
Classification Name and Reference:	Intramedullary Fixation Rod, 21 CFR §888.3020

Predicate Device Identification

The Osteo IC Humeral Nail (to be renamed the T2 Humeral Nail System) is a cylindrical, cannulated titanium alloy tube, slightly bowed to accommodate the shape of the humerus. The Osteo IC Humeral Nail may be inserted into the humeral canal using either a retrograde or antegrade surgical approach.

Description of Device Modification

The design change involves changing the screw hole configuration, adding partially threaded screws, extending the nail length range and changing the thread length and slot pattern to allow for the Advanced Locking Mode used in the T2 Tibial Nails. The 4 mm diameter T2 Locking screw, fully threaded will be compatible with the T2 Humeral Nail System.

Intended Use

The subject T2 Humeral Nail System, like the predicate Osteo IC Humeral Nail System, is a fracture fixation device comprised of humeral nails and the related locking screws, compression screws, and end caps. The subject and predicate devices are intended to provide strong and stable internal fracture fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

Statement of Technological Comparison:

FEA analysis demonstrates the comparable mechanical properties of the subject T2 Humeral Nail System to the predicate Osteo IC Humeral Nail System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 2 2001

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K011529
Trade Name: T2 Humeral Nail System
Regulatory Number: 888.3020
Regulatory Class: II
Product Code: HSB
Dated: May 15, 2001
Received: May 17, 2001

Dear Ms. Ariemma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011529

Device Name: T2 Humeral Nail System

Indications for Use

The use of the T2 Humeral Nail System is intended to aid in the alignment and stabilization of humeral fractures. The use ofthis system indicated for diagonal and short oblique fractures of the humeral diaphysis as well as fractures of the metaphyseal and some comminuted humeral fractures. The T2 Humeral Nail System is intended for single use only.

Indications:

- Fractures of the humeral shaft.
- Non-unions
- Malalignments
- Pathological humeral fractures
- Impending pathological fractures

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011529